

Application No. 10/748,933
Amendment dated SEPTEMBER 1, 2006
Reply to Office Action dated June 2, 2006

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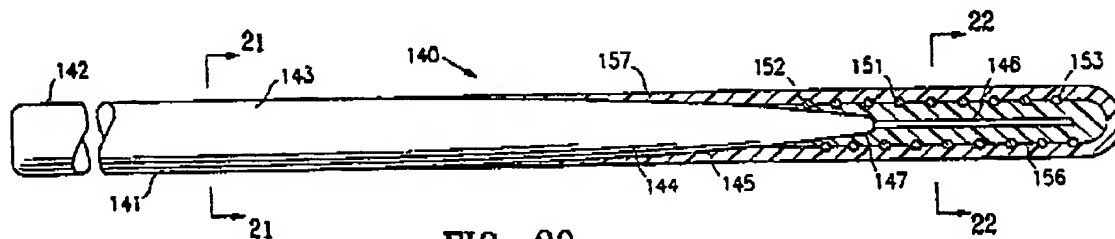
REMARKS

The Applicants have carefully reviewed the Office Action dated November 25, 2005. Claims 55-58 have been canceled; claims 23-54, 61 and 62 have been withdrawn. As such, claims 1-22, 59 and 60 remain under consideration. Claims 1 and 14 have been amended with this response.

Remarks Regarding Rejections Under 35 U.S.C. §103

Claims 1-7, 12-17, 21-22 and 59-60 are rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson et al., U.S. Patent No. 6,673,025 (hereinafter "Richardson"). Applicants respectfully traverse this rejection, and the comments made by the Examiner in making this rejection. In order for a combination of references to render a claim obvious, each and every element of the claim must be present in the cited prior art. See M.P.E.P. §2143.03.

The Examiner makes reference to Figure 20 of Richardson, which shows a guidewire 140 having an elongate core member 141, and a helical coil 151 is disposed about the distal section 143 of the elongate core member 141. A first polymer layer 156 is disposed about the distal section 143 of the elongate core member 141 and the coil 151. A second polymer layer 157 is disposed about an outer surface 161 of the first polymer layer 156. See, for example, column 19, line 65 through column 20, line 12. As shown in Figure 20, both the first polymer layer 156 and the second polymer layer 157 are disposed along the length of the coil, and both of these polymer layers 156/157 extend distally of the helical coil distal end 153. To aid in the explanation, Figure 20 is included below:



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As can be seen, the distal end of the first polymer layer 156 extends distally of the helical coil distal end 153. In contrast, claim 1 recites, in part, a guidewire comprising a core member, a tubular member connected to the core member and a coil member connected to the tubular member. In claim 1, the distal end of the tubular member extends distally beyond the distal end of the core member, and the distal end of the coil member extends distally beyond the distal end of the tubular member. Claim 14 recites, among other elements, a guidewire comprising a core member and a distal assembly including a tubular member and a coil member connected to the tubular member. In Claim 14, the distal assembly is connected to the core member, extending distally beyond the distal end of the core member, and the coil member extends distally beyond the distal end of the tubular member. In Figure 20 of Richardson, even if the first polymer layer 156 could be considered the tubular member of claims 1 and 14, the helical coil distal end 153 does not extend beyond the distal end of the first polymer layer 156. In fact, the opposite is true; the helical coil distal end 153 actually remains proximal of the distal end of the first polymer layer 156, as shown above in Figure 20. Because all elements of claims 1 and 14 are not disclosed in Richardson, Applicants respectfully assert that, for at least this reason, these claims are allowable over this reference. Because they are dependent on claims 1 and 14 and because they contain additional patentably distinct elements, Applicants assert that claims 2-7, 12, 13, 15-17, 21 and 22 are also allowable over Richardson. Additionally, the applicants do not concede that the Examiners characterization of Richardson with respect to the dependent claims is accurate.

Claim 59 recites, in part, a medical device with a distal assembly, the distal assembly including a tubular member and a ribbon or wire connected to and extending distally of the tubular member. It appears as though the Office Action is equating the helical coil 151 of Richardson with the ribbon or wire of claim 59. However, as shown above in annotated Figure 20 of Richardson, the helical coil distal end 153 does not extend distally of the first polymer layer 156. Thus, because the helical coil does not extend distally of the distal end of the first polymer layer 156, the helical coil of Richardson cannot be the ribbon or wire of claim 59. Because Richardson is missing at least this element of claim 59, Applicants assert that this claim is allowable over this reference for at least this reason. Because it is dependent on claim 59 and

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because it contains additional patentably distinct elements, Applicants also assert that claim 60 is allowable over this reference.

Claims 8, 11, 18 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson in view of Palmer et al., U.S. Patent No. 6,544,231 (hereinafter "Palmer"). Applicants respectfully traverse this rejection, and the comments made by the Examiner in making this rejection. As mentioned above, Richardson does not disclose each and every element of claims 1 and 14. In addition, Palmer does not disclose the subject matter that is missing from Richardson. Because they depend on claims 1 and 14 and because they recite additional patentably distinct elements, all elements of claims 8, 11, 18 and 20 are also not disclosed by this combination. Therefore, these claims are allowable over these references for at least this reason.

Claims 9, 10 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Richardson in view of Palmer, and further in view of Cook et al., U.S. Patent No. 5,213,111 (hereinafter "Cook"). Applicants respectfully traverse this rejection, and the comments made by the Examiner in making this rejection. As mentioned above, the combination of Richardson and Palmer does not disclose each and every element of claims 1 and 14. In addition, Cook does not disclose the subject matter that is missing from the combination of Richardson and Palmer. Because they depend on claims 1 and 14 and because they recite additional patentably distinct elements, all elements of claims 9, 10 and 19 are also not disclosed by this combination. Therefore, these claims are allowable over these references for at least this reason.

Claims 1-4, 13-16, 22 and 59-60 were rejected under 35 U.S.C. §103(a) as being unpatentable over de Toledo, U.S. Patent No. 5,065,769 in view of in view of Buchbinder et al., U.S. Patent No. 4,757,827 (hereinafter "Buchbinder"). Applicants respectfully traverse this rejection, and the comments made by the Examiner in making this rejection. In order for a combination of references to render a claim obvious, there must be some suggestion or motivation in the prior art to make the proposed combination and each and every element of the claim must be present in the cited prior art. See M.P.E.P. §2143.01 and §2143.03.

M.P.E.P. §2143.01, part III states that "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Neither of these references provides a motivation or suggestion

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to connect the tube and the coil of de Toledo, and thus this combination cannot be used to render these claims obvious.

As shown in Figure 1 of Buchbinder, a deflection wire 3 is arranged axially in a lumen formed by tubing 2 and a spring coil 7. See, for example, column 3, lines 15-18. Moving the deflection wire 3 within the flexible tubing 2 and the spring coil 7 can deflect the tip of the guidewire. See, for example, column 2 lines 29-46. Thus, the deflection wire 3 of Buchbinder is apparently longitudinally moveable within the flexible tubing 2 and the spring coil 7. In contrast, the core is fixed to the inner coil in de Toledo. See, for example, column 3, lines 3-4. Simply put, there is no motivation to combine the structure of Buchbinder, where the deflection wire is moveable in order to make the guidewire tip deflectable, with the structure of de Toledo, where the core is fixed to the inner coil. Making such a modification ignores the differing purposes of, and the differing modes of operation of, both Buchbinder and de Toledo.

Additionally, according to M.P.E.P. §2141.03, VI, when determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782 (Fed. Cir. 1983). According to these cases, the references as a whole must be examined. See *id.* When combining references for the purposes of obviousness, the focus is not properly on one isolated aspect of a reference. The portion of the reference that is being used must be taken in the context of the entire prior art reference and compared to the claim as a whole.

In this case, Buchbinder discloses a lumen that is formed by a flexible tubing 2 and a spring coil 7. A deflection wire can be disposed within, and can be movable within, the lumen in order to facilitate deflection of the guidewire tip. The Office Action apparently isolates the tube-to-coil attachment aspect of Buchbinder, combines this tube-to-coil attachment aspect with the structure of de Toledo, and states that the two references together disclose a core member that is connected to a tubular member that is connected to a coil, as recited in claim 1. In addition, it is apparently asserted that the tube-to-coil aspect of Buchbinder can be combined with the structure of de Toledo, resulting in a distal assembly that is connected to a core member or a shaft, where

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the distal assembly includes a tubular member along with a coil member or a ribbon or wire, as recited in claims 14 and 59.

However, isolating only the tube-to-coil attachment aspect of Buchbinder completely ignores the context of Buchbinder, and Applicants respectfully assert that this is an improper use of this reference. Buchbinder does not disclose, in isolation, the aspect of a tube-to-coil attachment. Using this isolated element of Buchbinder in this manner would appear to render obvious any connection between a tube and a coil in nearly any manner and in nearly any part of a medical device. According to *Stratoflex* and *Schenck*, pulling such an isolated element out of a reference, out of context, is not proper. Instead of disclosing the tube-to-coil attachment aspect in isolation, Buchbinder actually speaks to using a tube and a coil to form a lumen, and disposing a deflection wire in this lumen. The deflection wire can be longitudinally moved within the lumen in order to deflect the tip of the guidewire. As stated above, Buchbinder does not disclose, in isolation, attachment of a tube to a coil. What Buchbinder does disclose is the formation of a lumen using a tube and a coil and disposing a deflection wire in the lumen such that the deflection wire can be moved in order to deflect the tip of the guidewire. Taking into account the entire disclosure of Buchbinder, de Toledo modified by Buchbinder would actually result in a guidewire with a tube attached to a coil, forming a lumen in which a core is moveable.

There are several issues with making such a modification of de Toledo. For one thing, such a modification would be contrary to statements in de Toledo (see column 3, line 4, stating that the core is fixed to the inner coil). Thus, there is no motivation to modify de Toledo in this manner. In addition, this modification of de Toledo would not result in the invention of claims 1, 14 or 59, which state, in part, that the tubular member is connected to the core member (claim 1) or that a distal assembly is connected to a core member or a shaft (claims 14 and 59). Thus, de Toledo and Buchbinder together do not result in the combination of elements as recited in claims 1, 14 or 59. Because they are dependent on claims 1, 14 and 59 and because they contain additional patentably distinct elements, Applicants also assert that claims 2-4, 13, 15, 16, 22 and 60 are also patentable over these references.

Claims 8, 18 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over de Toledo in view of Buchbinder further in view of Palmer et al., U.S. Patent No. 6,544,231 (hereinafter "Palmer"). As mentioned above, there is no motivation to combine de Toledo and

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Buchbinder, and these references do not disclose each and every element of claims 1 and 14. In addition, Palmer does not contain either the motivation to combine or the elements of claims 1 and 14 that are missing from de Toledo and Buchbinder. As such, Applicants respectfully assert that claims 8, 18 and 20, which depend from claims 1 and 14, are also allowable over these references.


Claims 9 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over de Toledo in view of Buchbinder in view of Palmer further in view of Cook et al., U.S. Patent No. 5,213,111 (hereinafter "Cook"). As mentioned above, there is no motivation to combine de Toledo and Buchbinder, and these references do not disclose each and every element of claim 1. In addition, neither Palmer nor Cook contains either the motivation to combine or the elements of claim 1 that are missing from de Toledo and Buchbinder. As such, Applicants respectfully assert that claims 9 and 10, which depend from claim 1, are also allowable over these references.

Reexamination, reconsideration, and withdrawal of the outstanding objections and rejections are respectfully requested. It is submitted that all pending claims are now in condition for allowance, and the issuance of a Notice of Allowance in due course is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their attorney,

Date: September 1, 2006


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